## REMARKS

The Office Action dated October 6, 2004 has been carefully reviewed, and the following remarks are made in response thereto. In view of the above following remarks, Applicants respectfully request reconsideration and reexamination of this application and timely allowance of the pending claims.

## Summary of the Office Action

1. Claims 32 to 38 and 55 to 56 are pending.

2. Claims 32 to 38 and 55 to 56 were rejected under 35 U.S.C. 112 (first paragraph) as failing to comply with the written description requirement because these claims purportedly contain new matter.

3. Claims 32 to 38 and 55 to 56 were rejected under 35 U.S.C. 103(a) as purportedly being unpatentable over U.S. Patent 5,935,727.

## Response to the Office Action

## Rejection under 35 U.S.C. 112 (first paragraph)

The Office Action alleges that Applicants have failed to comply with the written description requirement because claims 32 to 38 and 55 to 56 purportedly contain new matter. The Examiner purports that the specification does not have adequate written description for a computer system comprising a database containing information concerning the expression levels of at least ten, fifty or seventy different nucleic acid molecules.

Applicants disagree and bring to the attention of the Examiner that with respect to numerical range limitations, any analysis by the Examiner must take into account which ranges one skilled in the art would consider inherently supported by the discussion of the original disclosure. The Examiner indicates that original claims 32 and 33 provide for a computer system limited to a database to provide "at least two genes" (see Office Action at page 3). Applicants bring to the attention of the Examiner that the experimental data disclosed in Applicants' specification in Tables 1 thru 6 provide adequate written support for a database with at least fifty or seventy, or for any number of nucleic acid molecules up to the total number disclosed in the table. For example, Table 2 discloses over seventy sequences and therefore provides adequate written support for any number greater than seventy, up to the total number of sequences in this table. In view of this disclosure, Applicants submit that claims 32 to 38 and 55 to 56 are adequately supported by the specification and request withdrawal of the rejection.

The Examiner has rejected amended claim 1 as containing new matter for reciting a computer system comprising software that allows a user to compare data from a sample to data in a database. Claim 1 has been cancelled, therefore that Examiner's comment is incorrect. In the event the Examiner is referring to the amendment in claim 32, Applicants will adress this rejection as it may apply to this claim.

The Office Action purports that the specification does not provide specific support for a computer system comprising software for comparing sample information to a database. Applicants disagree and bring to the attention of the Examiner that the disclosure in the specification which describes "database software and packaged information include[ing] the expression results of Tables 1 to 6" (see page 21, lines 11 to 12). The specification further discloses databases and software designed for use with microarrays and incorporates by reference multiple U.S. patents disclosing such software (see page 21, lines 24 to 32). In addition, the specification discloses a specific type of software (Affymetrix Expression Data Mining Tool "EDMT") in the experimental section that was used to compare sequences to a database (see page 23, lines 11 to 26). In view of this disclosure, Applicants submit that claim 32 is adequately supported by the specification and request withdrawal of the rejection.

**Claim Rejections under 35 U.S.C. 103**

Claims 32 to 38 and 55 to 56 were rejected under 35 U.S.C. 103(a) as being unpatentable over Maslyn *et al.* (U.S. Patent 5,953,727). The Office Action purports that the sequence and data expression levels recited in the claims do not have a functional relationship with the hardware recited in the claims and as such they purportedly do not distinguish the claims from the prior art.

The Examiner states that the oligonucleotides recited in the claims do not distinguish the claimed system from the prior art and the claims are obvious (see Office Action at page 6). Applicants bring to the attention of the Examiner that the claims do not recite the term "oligonucleotide" at any time. In the event the Examiner is referring to the nucleic acid sequences (SEQ ID NO: 1 to 1124) set forth in the claims, Applicants will address this rejection as may be necessary.

Applicants bring to the attention of the Examiner that the cited reference does not disclose nor suggest any aspect of BPH. Even without reference in the claims to the nucleic acid sequence information that the Examiner considers to be non-functional, the claimed inventions encompass a database concerning expression levels in BPH tissue. There is no disclosure or suggestion to utilize Masyln *et al.* for purposes related to BPH and therefore Examiner is using impermissible hindsight reasoning to apply the cited reference.

Applicants also disagree with the Examiner's finding that the reference to the nucleic acid sequences constitutes non-functional subject matter. Foremost, non-functional descriptive matter relates to 35 U.S.C. 101 and not 35 U.S.C. 103(a). Any rejection employing rational relying on non-functional decriptive material is improper under 35 U.S.C. 103(a). It therefore appears that the Examiner is providing an impermissible standard when determining the metes and bounds of the pending claims.

Even arguendo, assuming the application of the standard is permissible under 35 U.S.C. 103(a), the finding of non-functional descriptive material in the claims is improper. The interaction of the sequence and expression information constitutes a functional limitation in the claims because the computer system enables the user to identify whether the expression of a nucleic acid sequence is up- or down-regulated. Thus, comparison of one nucleic acid sequence to other sequences in the database generates a subset of sequences with similar expression parameters to the query sequence. Generation of this subset of sequences with similar expression levels constitutes a functional interrelationship between the database and the software. In view of the above comments, Applicants request withdrawal of the rejection.

**Information Disclosure Statement**

In accordance with the Examiner's request, attached are replacement copies of the documents cited in the Information Disclosure Statements filed on June 11, 2002 and August 21, 2002. Applicants respectfully request that the Examiner consider the listed documents and evidence that consideration by making appropriate notations on the attached replacement PTO-1449 forms.

**Conclusion**

The foregoing remarks are being made to place the application in condition for allowance. Applicants respectfully request reconsideration and timely allowance of the pending claims. A favorable action is awaited. Should the Examiner find that an interview would be helpful to further prosecution of this application, she is invited to telephone the undersigned at her convenience.
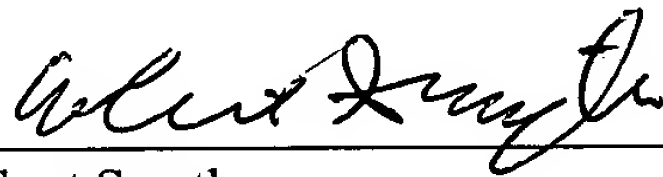
If there are any fees due in connection with the filing of this amendment, please charge the fees to our Deposit Account No. 50-310. If a fee is required for an extension of time under 37 C.F.R. 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

**Except** for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **constructive petition for extension of time** in accordance with 37 C.F.R. 1.136(a)(3).

Dated: **March 7, 2005**

Morgan, Lewis & Bockius LLP
Customer No. **09629**
1111 Pennsylvania Ave., N.W.
Washington, D.C. 20004
202-739-3000

Respectfully submitted
**Morgan, Lewis & Bockius LLP**

Robert Smyth
Registration No. 50,801